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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/554,784	06/05/00	DE BOER M	DEBOER2

EXAMINER	
DECLOUX, A	
ART UNIT	**PAPER NUMBER**
1644	11

000545
HANDAL & MOROFSKY
80 WASHINGTON STREET
NORWALK CT 06854

HM12/0927

DATE MAILED: 09/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/554,784	DeBoer et al.
Examiner	**Art Unit**
DeCloux, Amy	1644

-- Th MAILING DATE of this communication app ars on th cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-10 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-10 are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Detailed Action

1. Applicant's submission of the instant application as a 371 is acknowledged, however Claim 1 does not provide a technical feature that is distinguished over the prior art, as evidenced by EP-A-0 759 466 (F. Hoffman La Roche) 26 FEB 1997 (IDS), who teach monoclonal antibodies to IL-12 beta2 receptor protein or fragments thereof which can be used in combination with another antibody such as one to IL-2 receptor as a pharmaceutical comosition for the treatment of autoimmune disfunction, (see entire patent, especially page 7, lines 56-59 and page 8, lines 13-19 and 20-21, and claim 24). Though by EP-A-0 759 466 does not teach that said antibodies prevent IL12R B2 chain-mediated STAT4 phosphorylation, said antibodies inherrently may possess said properties, absent evidence to the contrary. Therefore, the instant invention lacks Unity of Invention.

2. A restriction is required under 35 USC 121 and 372 between one of the following groups:

I. Claims 1-3 and 8, drawn to a monoclonal antibody that can bind to the IL12R beta chain, and pharmaceutical composition thereof, classified in Class 530, subclass 388.75, Class 424, subclass 144.1,

II. Claims 1, 4-5 and 8-9, drawn to a combination of a monoclonal antibody, or part thereof, that can bind to the IL12R beta chain, and an autoantigen, or fragment or modified form thereof, and pharmaceutical composition thereof, classified in Class 530, subclass 388.75, Class 424, subclasses 144.1 and 184,

III. Claims 1 and 6-7, drawn to a combination of a monoclonal antibody, or part thereof, that can bind to the IL12R beta chain, and a second monoclonal antibody, classified in Class 530, subclass 388.75,Class 424, subclass 144.1, or

IV. Claim 9, drawn to a method for treating a autoimmune diseases, classified in Class 424, subclasses 144.1 and 184.

Note: Each group will be examined only to the extent of the elected invention.

The inventions are distinct, each from the other because:

2. Groups I-III are different products. The products of Groups I/III and II differ with respect to the presence of an auto-antigen in the latter group, while the products of Groups I/II and III differ with respect to the presence of a second monoclonal antibody in the latter group, while the products of Groups I and II/III differ with respect to the absence of a recitation of either an auto-antigen or a second monoclonal antibody. The dispparate components of each group conferring a distinct structure and function to each group. Therefore Groups I-III are patentably distinct.

4. Group II and Group IV are related as product and process of use. The inventions

can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product, a a combination of a monoclonal antibody, or part thereof, that can bind to the IL12R beta chain, and an autoantigen, or fragment or modified form thereof, and pharmaceutical composition thereof, as claimed, can be used in a method of affinity purification, as well as in a method for treating a autoimmune diseases.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because a search in the non-patent literature of any of these distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at

paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers **(other than elections)** should be faxed to Technology Center 1600 via the PTO Fax Center located In Crystal Mall 1. The faxing of such papers must conform with the notice published In the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner
Group 1640, Technology Center 1600
September 27, 2001

PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER